



Physician's Folio-Pharma Inc.

March 16, 2001

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COMMENT

Re Docket #00N-1269

Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels (Dec. 22, 2000)

My name is L. Anthony Lupi, President and Chairman of Physician's Folio-Pharma, Inc., producers of the first drug sampling system to ever obtain patents in the industry. I'd like to voice my strong unequivocal support of 21 CFS Part 201 with one caveat – the proposal should and must be amended to include product sample labeling. More than 10 years of independent research indicates that this is where the problem of improperly educating consumer often starts.

Free prescription drug samples do not contain adequate information in their packaging to keep consumers safe from harm. Doctors routinely fail to make copies of the drug information inserts that come with bulk sample packages to disseminate to every patient. Once samples are delivered to the doctors' offices, protection and control measures end. After a bulk sample box or "sleeve" is signed for by the physician or aide, office workers, their friends and family members are free to use sample products without the benefit of a consult or complete information about the drug. Far too often, this practice results in serious drug reactions, interactions and/or death.

The AMA estimates that about 90 million Americans have difficulty comprehending medical information and acting on it. In an AMA national leadership conference held in March, professionals agreed that results can be devastating – visits to emergency rooms, increased likelihood of complications, even death. The country's largest organization of physicians estimates that low health literacy costs the health care system \$73 billion a year in unnecessary doctor visits, hospitalizations and longer hospital stays, and that estimate does not factor in expenses associated with malpractice lawsuits.

I have spent the last 10 years developing and obtaining patents for a drug sampling system which, in addition to saving lives, saves pharmaceutical manufacturers billions of dollars in marketing costs. Each and every product sample contains complete easy-to-read information about the drug it contains and a means by which doctors can write a prescription on-the-spot. This results in well-informed consumers and the writing of more controlled prescriptions – a tremendous value to both product manufacturers and users. Other Physician's Folio-Pharma products include customer coupons and a means by which pharmacists can obtain valuable patient information. The time has come for a revamping of the entire drug sampling process.

00N-1269

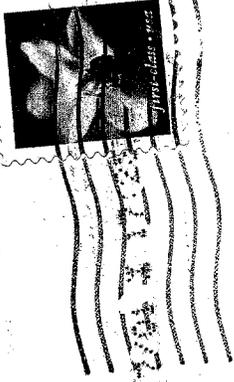
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There are far too many lives at stake and far too much waste inherent in the current system. It is my opinion that the proposed rule will not be complete without the inclusion of drug sample labeling.

Respectfully submitted,
L. Anthony Lupi.
President and Chairman
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